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May 10, 2021

**Centers for Disease Control and Prevention  
1600 Clifton Road NE, MS-H24-8  
Atlanta, GA 30329-4027  
Attn: May 12, 2021 ACIP Meeting.**

**SUBJECT:** Comments – 85 FR 16949, EUA 27034, Study BNT162-01 & Study C4591001, FDA Docket Nos. **CDC-2021-0049**, FDA-2020-D-1136, FDA-2020-D-1137 and FDA-2020-D-1370

Dear Sir or Madame:

Coronavirus pandemic (COVID-19) remains a global threat to humanity that calls for experts, policy-makers, and governments to confront several aspects that go well beyond the health and well-being consequences of this pandemic. The FDA plays a pivotal role in the lives of not only Americans, but to peoples all over the world. I believe the chaos the world has been suffering with during COVID-19 for over a year will be eased and overcome very soon (hopefully), with the aid of the thoughtful and considered actions by the FDA, as it has from the very beginning. Because of this significant role of the FDA and CDC, I am writing to raise my concerns on the following issues below, which have begun to threaten the entire world towards a chaos even bigger than the pandemic itself. This letter expresses my trepidation on certain medical applications and decisions, despite contrary scientific truth shown by countless scientific observations and publications during this pandemic. Besides numerous crucial global health problems created in this pandemic, the following issues seem to be the cornerstones of this debate which need extra attention. Otherwise, the scar of humanity opened nowadays will turn to be unhealable, even gangrenous. My main concerns are:

- A)** Vaccinating children as young as 12 (may be even younger) (President Joe Biden's announcement on May 4th) is premature and ill-advised prior to more long-term study
- B)** False positivity of PCR tests may lead to unnecessary isolation and even therapy
- C)** Vaccine certificate for travel and work
- D)** The socio-economic implications of the COVID-19.

I am a medical microbiologist and biotechnology expert with extensive experience in cell cultures, cell culture / vaccine contaminations over two decades (1-4), and was nominated for a Nobel

medical prize in 1998. I have been invited by NIH twice to describe potential vaccine contamination and briefing on the research of toxic nanoparticles on mammalian cell cultures and patents (Numbers 20070141055, 20070134814, 20050036904 and 6706290) for eradication of these contaminants from biopharmaceutical products used in vaccine production. During my work at NASA's Johnson Space Center in Houston, Texas, my team applied for FDA approval for our treatment of pathological calcification in the human body caused by this particles. Therefore, I know how difficult it is to obtain approval of the FDA for any product, and how much scrutiny is applied for every single piece of scientific evidence. It is not lost on me, and should not be lost on anyone, that the treatment we proposed at that time (proven by research at NASA, 4 different countries and 5 highly respected institutions), was a cure for exponentially more deaths and sicknesses than COVID-19 (heart disease/number one killer of humanity/one death every 30 seconds/30 milyon death annualy), yet the difference and approach between ours and COVID proposals is stark and disturbing.

It is not an exaggeration if I say that 'I learned approaching every problem in a molecular level during our FDA application for our discovery, and it became my life philosophy'. By following the same sensitive path, I listed my concerns and reasons for the future COVID-19 protection plan which will take shape with certain FDA and CDC approvals. I will be available from my contact info for further information if needed.

Thank you for all your services and your time.

Respectfully,

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## CONCERNS AND SCIENTIFIC BASES FOR THE CONCERNS

### A. RUSH FOR THE DECISION ON VACCINATING SMALL CHILDREN

In my professional life, I have been known as a vaccine supporter for decades. I gave lectures about the methodology of vaccine preparation, both the importance of vaccines and their benefits in medical schools in Europe and in the United States. However, I always underlined the importance of safety guidelines and the importance of proper clinical trial phases of vaccines before offering them for public use.

While COVID-19 vaccinations offer the promise of a return to the usual standards of healthcare, the vaccine-based solution needs sufficient population coverage. It requires acceptable policy, operational, and logistical actions. However, at the current phase of the COVID-19 pandemic, it is essential to discriminate between those who will benefit most from the vaccination and those who may have reasonable concerns regarding vaccination. It is not deniable that FDA and the CDC play a critical role in protecting not only the United States, but entire world from threats such as emerging infectious diseases, including COVID-19 pandemic. We scientists, who are experts in microbiology, infectious diseases, and epidemiology, know the necessity of an Emergency Use Authorization (EUA) for vaccines in pandemics. We also know that EUA vaccines require a consent letter from each adult volunteer and is highly risky and unethical for small children (before Phase-3 clinical trials). This is especially true when there are scientific reasons showing it is both unnecessary and may result in adverse effects

***Here are only few examples what science says:***

1. During Covid-19 pandemic, it has been shown that young children account for only a small percentage of COVID-19 infections (5). Even when they are infected with SARS-CoV-2, children are most likely to experience mild or asymptomatic illness (6). So, children should be kept out of the vaccination-need group.
2. Many molecular research papers concentrated on the reason for their better immune response compared to adults. (7). Because:
  - a. 29-50% of the children develop COVID-19 symptoms and antibodies specific to SARS-CoV-2 but never test positive for the virus on a standard RT-PCR test (8-11). Because children's immune systems see the virus and 'destroy' really quick and effective immune response that shuts it down, before it has a chance to replicate to the point that it comes up positive on the swab diagnostic test. Their immune system handles 'natural' coronavirus infection better than vaccines, the latter of which are not completely proven by FDA.

- b. It was shown that COVID-19 infected 18 years old or younger children produce antibodies for SARS-CoV-2 spike protein, which the virus use to enter cells. Adults generated similar antibodies, but also developed antibodies against the nucleocapsid protein, which is essential for viral replication. Nucleocapsid protein is typically released in significant quantities only when a virus is widespread in the body. The children mostly lack nucleocapsid-specific antibodies because apparently they aren't experiencing widespread infection. Children's immune responses seem to be able to eliminate the virus before it replicates in large numbers (12). Thus, they do not need to be vaccinated.
    - c. Children's T cells always have a greater capacity to respond to new viruses, e.g., Coronavirus. (13). They do not need extra virus antigens to be injected for preparing their immune system.
    - d. Children have a strong innate immune response towards Coronavirus (14). There is no need to shock their perfectly innate immune system with EUA vaccines.
  3. When children are exposed to the Coronavirus, they receive a smaller dose than adults, because their noses contain fewer ACE2 (angiotensin-converting enzyme 2) receptors, which the virus uses to gain access to cells. This might also explain why COVID-19 is less prevalent in children than in adults (15). Therefore from the very beginning of pandemics, children were not listed in risk groups for COVID-19. EUA vaccines are recommended mostly for risk groups and children were never listed under that group.
  4. Guillain-Barré syndrome (GBS) is an acquired disorder of the peripheral nerves, described best as a polyradiculoneuropathy. With the widespread eradication of poliomyelitis, GBS is the most common cause of acute and subacute flaccid paralysis in infants and children. The disorder is characterized by progressive, symmetrical, usually ascending weakness, and diminished or absent reflexes. Diffuse pain also is a common feature in many children with GBS, at times delaying accurate diagnosis. GBS was thought previously to be an inflammatory disorder that affected only the myelin sheath, resulting in diffuse demyelination. However, it is now recognized that the process can also attack the axon, leading to degeneration of the nerve itself. GBS is an autoimmune disorder that causes the body's immune system to attack part of the nervous system. This can occur after a viral infection, surgery, injury, or, sometimes, as a reaction to a vaccine. About 2 out of 3 people who develop symptoms of GBS do so a few days or weeks after diarrhea or a respiratory illness. (16). Therefore symptoms of GBS might be mistakenly evaluated as simple vaccine side effects or even Covid-19.

Although GBS is accepted as very rare side effect of COVID-19 vaccinations, there are enough (and growing in number) medical reports urging FDA and CDC to keep an eye on this issue. Emerging data indicate that Covid 19 vaccines can trigger not only GBS, but

other autoimmune neurological diseases necessitating vigilance for early diagnosis and therapy initiation (17-22)

I would like to remind FDA and the CDC that after many years use, FDA has collected the medical reports and added Guillain-Barré syndrome warning to GlaxoSmithKline's shingles vaccines (23) COVID-19 vaccines developed for pandemics have been applied for less than a year, and have still not completed the Phase 3 clinical trials! Medical observation and past experiences with other vaccines show that the risk of vaccinating the children, the future of all the world, is certainly a greater risk than a COVID-19 infection.

5. Children are known to be a 'reservoir' of respiratory infections/seasonal coronavirus infection (HCoV). Multiple independent assays demonstrate the presence of preexisting antibodies against other respiratory viruses, recognizing SARS-CoV-2 in uninfected individuals. Identification of conserved epitopes in S2 targeted by neutralizing antibodies may be a good explanation why the infection rate is lower in children compared to adults. Together with preexisting T cell (24-25) and B cell (26). Cross-reactivity between seasonal HCoVs and SARS-CoV-2 may have important ramifications for natural infection. A possible modification of COVID-19 severity by prior HCoV infection may account for the age distribution of COVID-19 susceptibility, in which higher HCoV infection rates in children than in adults(27). These results show that it is very likely that especially children can raise natural immune response towards new viruses and the risk of serious health effects of coronavirus infection is much lower than the vaccines which is still in an EUA category!
6. The broad spectrum of interactions between autoimmune inflammatory diseases (AIID) and SARS-CoV-2 infection are unpredictable, and the mechanism underlying this relationship remains poorly understood. Like in other viral infections, COVID-19 could trigger an AIID flare. Nevertheless, beyond rheumatologists' expectations, COVID-19 is linked to autoimmune and autoinflammatory sequelae, raising questions about its long-term immune-mediated consequences and complications (28). Either because of coronavirus infection or mRNA vaccines, SARS-CoV-2 sequences can be reverse-transcribed and integrated into the DNA of human cells. (29). If a cell with an integrated and expressed SARS-CoV-2 sequences survives and presents a viral- or neo-antigen after the infection is cleared, this might engender continuous stimulation of immunity without producing infectious virus, and could trigger a protective response or conditions such as autoimmunity (30). As Moderna's chief medical Officer Dr. Tal Zaks mentions in his TED talk and interviews 'mRNA vaccines are designed to hack the software of life' (31). It might be promising technology for fixing countless diseases in the future, but it is not ready YET for protecting healthy kids from a virus which has not shown life threatening for them.

7. Although the COVID-19 pandemic has been going on for over a year, public/parents who are planning to vaccinate their children are still ill-informed with incomplete 'Vaccine side effects.' What all public told is:

Following side effects could affect your ability to do daily activities, but they should go away in a few days:

- pain,
- redness
- swelling in the arm where you received the shot
- tiredness
- headache,
- muscle pain,
- chills,
- fever
- nausea

Before signing a consent of EUA vaccines, every individual (especially children, old population, patients with chronicle diseases and immucomprimsed patients) has a right to know that there might be unknown long term side effects within in following 2-3 years, including what those may be.

Scientific ethics calls for honesty and integrity in all stages of scientific practice.

## **B. FALSE POSITIVITY OF PCR TESTS MAY LEAD TO UNNECESSARY ISOLATION AND EVEN THERAPY**

According to numerous studies (32-38) continuous or recurrent positive severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) PCR tests have been reported in samples taken from patients weeks or months after recovery from an initial infection. Furthermore, no replication-competent virus was isolated or spread from these PCR-positive patients, and the cause for the prolonged and recurrent production of viral RNA remains unknown. If integration and expression of viral RNA are fairly common, reliance on extremely sensitive PCR tests to determine the effect of treatments on viral replication and viral load may not always reflect the ability of the treatment to fully suppress viral replication. This is because the PCR assays may detect viral transcripts that derive from viral DNA sequences that have been stably integrated into the genome rather than infectious virus.

I Know that the FDA has announced the false positive PCR issue earlier (39). However, it was overlooked and never discussed throughly. Since then, there is more piling up reports and scientific news about this issue(40-43).

This truth needs to be dicussed in a debate with world-wide known experts organised by the FDA and CDC. One of the responsibilities of the FDA and CDC is protecting public

health. It is critical in this context when there is a vicious cycle of where the PCR test are misused, or applied for purposes and in ways never intended. At some point, this completely undermines medical services integrity and credibility.

### **C. VACCINE CERTIFICATE FOR TRAVEL AND WORK**

One of President Biden's Executive Orders aimed at curbing the pandemic asks government agencies to "assess the feasibility" of linking coronavirus vaccine certificates with other vaccination documents, and producing digital versions of them.

Similar applications started all over the world. For example Denmark's government said in early February that in the next three to four months, it will roll out a digital passport that will allow citizens to show they have been vaccinated.

As much as it sounds normal, along with the soundbytes that this has been done before, there is again a very big missing point that differentiate the current situation! None of the required vaccines for work, school and traveling was at the EUA stage. They all were tested over 5 years, and received 'full permission' from the FDA. If FDA and the CDC do not emphasize this missing point in the near future, it will set a dangerous new precedent, first by politicians and after that by complicit medical authorities who seek to undermine the reasons why time is needed for full approval, and to rush is against science and any medical norms!

### **D. THE SOCIO-ECONOMIC IMPLICATIONS OF THE COVID-19**

The COVID-19 pandemic has become challenging even for the most durable healthcare systems. To contain the severe acute respiratory syndrome coronavirus 2 spread, drastic restrictive measures were taken around the globe. Lockdowns, at the cost of economic slowdowns and restriction of human freedoms, seem to be the norm rather than the exception. Reorienting healthcare services to COVID-19 management in the already over-extended and underfunded health systems has limited their ability to hold other disease burdens. Furthermore, halting routine procedures and interventions, follow-up, and immunization programs has led to outbreaks of preventable transmissible diseases, raised cancer incidence, and created an increased number of complicated medical disorders in the late stages.

Social distancing, self-isolation and travel restrictions have led to a reduced workforce across all economic sectors, and caused many jobs to be lost. Schools have closed down, and the need for commodities and manufactured products has decreased. In contrast, the need for medical supplies has significantly increased. The food sector is also facing increased demand due to panic-buying and stockpiling of food products. In response to this global outbreak, we summarise the socio-economic effects of COVID-19 on individual aspects of the world economy.

COVID-19 has had an impact on social mobility whereby schools are no longer able to provide free school meals for children from low-income families, social isolation and school dropout

rates. It has also had a significant impact on childcare costs for families with young children. Additionally, there exists a wide disparity amongst populations with a higher income who are able to access technology that can ensure education continues digitally during social isolation.

When we need more science in this pandemic to address these issues, science STOPPED! Additionally, concerns have been raised regarding the number of scientific conferences that have been cancelled or postponed (44). These conferences are the key to scientific research in many disciplines, allowing dissemination of research as well as providing networking opportunities for collaboration and job-seeking. Many conferences have moved online, however these 'virtual conferences' are often not as amenable to networking and informal means of scientific communication. We often hear the mantra from politicians that we need to trust the science, but science is not static, and it is clear there has not been proper peer review or scientific debate during this pandemic.

Well, we all know these issues. There are countless issues more which probably would not fit into dozens of books. The depth of the issues is deeper than we read and understand. This letter is just one attempt at a reset, to get us to think about whether there are other solutions to approaching this pandemic, and how we might reinvigorate scientific investigation and debate about it outside those with a financial interest or a political agenda. As a scientist, I felt responsible to raise these concerns, and hope that someone with an objective and analytical mindset receives it. The point is that more than as a scientist, as a human being this is what I could do. Because I still have hope for humanity, and believe in vigorous scientific debate and review, I trust you will do the right thing, and will never forget your crucial role in ending this nightmare.

As writer Roy T. Bennett says 'Do what is RIGHT, not what is easy nor what is popular and accepted by many!'

Please remember, decisions announced by FDA and the CDC do not shape only our national health concerns, it is followed by the entire medical society of the world. Most importantly, our children's future is laying in the tip of your pen.

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